PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 227/04352	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/IL2005/000046	International filing date *(day/month/year)* 13.01.2005	Priority date *(day/month/year)* 15.01.2004
International Patent Classification (IPC) or national classification and IPC A61B5/00		
Applicant GLUCON INC. et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
15.11.2005	13.03.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Beck, E Telephone No. +49 89 2399-2964

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IL2005/000046

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-16	as originally filed
Claims, Numbers	
1-36	filed with telefax on 19.12.2005
Drawings, Sheets	
1/6-6/6	as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☒ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☒ the claims, Nos. 37
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-36
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-36
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-36
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: WO 02/15776 A

D3: US 2002/049374 A1

Document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and shows (the references in parentheses applying to this document):
apparatus for assaying an analyte in blood in a patient's blood vessel (abstract) comprising:

- a light provider comprising at least one light source that illuminates a tissue region in which a blood vessel is located with light that stimulates photoacoustic waves in the region (p.2, l.32 - p.3, l.13);
- at least one acoustic transducer that generates signals responsive to the photoacoustic waves (p.17, l.31 - p.18, l.7);
- a controller that receives the signals and processes them to determine which are responsive to photoacoustic waves that originate in the blood vessel and uses the determined signals to assay the analyte (p.18, l.7-20);

wherein, the light provider and at least one transducer define a field of view that overlaps the blood vessel, the field of view having a central region and a lateral extent greater than about 4 mm (p.17, l.6-12; fig.1 - it is indicated that the terms "field of view", "central region" and "lateral extent" are not clear; however, one can see that the dimensions of the extent of at least one light pulse transmitted by the light provider of D1 depends on the depth of penetration and at a certain depth has the size specified in claim 1).

The subject-matter of claim 1 differs from this known apparatus in that the light provider comprises optics for each of the at least one light source that configures light from the light source into a fan shaped light beam.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as to provide an apparatus for assaying an analyte in blood in a patient's blood vessel adapted to take correct measurements also in case of a misaligning displacement of the apparatus.

The apparatus of D1 comprises a light provider comprising optics for shaping a light beam (see D1: p.17, l.23-25). However, no indication for a fan shaped beam is given. Moreover, document D1 teaches away from a fan shaped beam telling about 'uniform and more symmetric illumination' (see D1: p.17, l.25-27), which suggests a cylindrical or cone shaped beam. Document D3 deals with an alignment mechanism in an apparatus for assaying an analyte. However, no use of a fan shaped beam in order to get a better alignment is suggested.
As a consequence, the person skilled in the art would not find any indications in the available prior art documents to modify the apparatus of D1 in the way set out in claim 1. Therefore, the subject-matter of claim 1 meets the requirements of the PCT with respect to inventive step (Art.33(3) PCT).

Claims 2-36 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

CLAIMS

1. Apparatus for assaying an analyte in blood in a patient's blood vessel comprising:

a light provider comprising at least one light source that illuminates a tissue region in which a blood vessel is located with light that stimulates photoacoustic waves in the region wherein the light provider comprises optics for each of the at least one light source that configures light from the light source into a fan shaped light beam;

at least one acoustic transducer that generates signals responsive to the photoacoustic waves;

a controller that receives the signals and processes them to determine which are responsive to photoacoustic waves that originate in the blood vessel and uses the determined signals to assay the analyte; wherein,

the light provider and at least one transducer define a field of view that overlaps the blood vessel, said field of view having a central region and a lateral extent greater than about 4 mm.

2. Apparatus according to claim 1 wherein the field of view has a lateral extent greater than or equal to about 6 mm.

3. Apparatus according to claim 1 wherein the field of view has a lateral extent greater than or equal to about 10 mm.

4. Apparatus according to any of claims 1-3 wherein the at least one light source comprises a plurality of light sources.

5. Apparatus according to claim 4 wherein the fan beams of the plurality of light sources are substantially parallel.

6. Apparatus according to claim 5 wherein the plurality of light sources are collinear.

7. Apparatus according to claim 5 wherein the plurality of light sources are configured in an array of rows and columns.

8. Apparatus according to any of claims 1-7 wherein the light provider comprises a mirror that receives light from the light source and reflects the received light to the tissue region and

wherein the mirror is rotatable about an axis and for different rotation angles of the mirror about the axis the fan beam illuminates a different portion of the tissue region.

9. Apparatus according to claim 8 and comprising a controller that controls the angle of the mirror to scan the tissue region with light from the light source.

10. Apparatus according to any of the preceding claims wherein the light provider comprises a light pipe having an input surface region to which at least one light source is coupled and an output surface region through which light that enters the light pipe from the at least one light source exits the light pipe.

11. Apparatus according to claim 10 wherein the light pipe has a shape of a planar plate having two large parallel face surfaces and narrow edge surfaces.

12. Apparatus according to claim 11 wherein the input surface region to which the at least one light source is coupled is a narrow edge surface of the light pipe.

13. Apparatus according to claim 12 wherein the output surface region from which light exits the light pipe is a narrow edge surface opposite the input surface region.

14. Apparatus according to any of the preceding claims wherein the at least one transducer comprises a plurality of transducers.

15. Apparatus according to claim 14 wherein the transducers are configured in an array of rows and columns of transducers.

16. Apparatus according to claim 14 or claim 15 and comprising a mounting plate, which is attached to the skin to acoustically couple the apparatus to the skin.

17. Apparatus according to claim 16 and wherein the transducers are mounted to the mounting plate.

18. Apparatus according to claim 16 wherein the mounting plate comprises a layer of piezoelectric material.

19. Apparatus according to claim 18 wherein each of at least two of the plurality of transducers comprises a different region of the layer of piczoelectric material sandwiched between a first and a second electrode.

20. Apparatus according to claim 19 wherein the first electrodes of each of the at least two transducers are substantially electrically isolated from each other.

21. Apparatus according to claim 20 whercin the second electrode of each of the at least two transducers comprises a different region of a same conductor.

22. Apparatus according to any of claims 1-21 wherein a transducer of the at least one transducer is acoustically coupled to the skin via an acoustic waveguide.

23. Apparatus according to claim 22 wherein the acoustic waveguide is an optic fiber.

24. Apparatus according to any of claims 1-23 wherein a light source of the at least one light source is optically coupled to the skin via an optic fiber that transmits light from the light source to the skin.

25. Apparatus according to claim 24 wherein a transducer of the at least one transducer is acoustically coupled to the skin by the optic fiber.

26. Apparatus according to any of the preceding claims wherein the controller controls the at least one transducer to acoustically image the blood vessel.

27. Apparatus according to any of the preceding claims wherein the controller processes signals generated by the at least one transducer responsive to acoustic energy from the photoacoustic waves to image the blood vessel.

28. Apparatus according to claim 27 wherein at least some of the light provided by the light provider is light at a wavelength at which light is strongly absorbed and or scattered by blood.

29. Apparatus according to any of claims 26- 28 wherein the controller uses the image to determine if the blood vessel is substantially aligned with the central region of the field of view.

30. Apparatus according to claim 29 wherein the apparatus comprises an indicator light and the controller controls the indicator light to generate an optical signal indicative of a degree to which the blood vessel is aligned with the central region.

31. Apparatus according to claim 29 or claim 30 wherein the apparatus comprises a speaker and the controller controls the speaker to generate an audio signal indicative of a degree to which the blood vessel is aligned with the central region.

32. Apparatus according to any of claims 26-30 wherein the apparatus comprises a display screen and the controller displays a fiducial mark representing the central region of the field of view and the image of the blood vessel on the screen and wherein a distance on the screen between the blood vessel and the fiducial mark represents a distance between the blood vessel and the central region.

33. Apparatus according to any of the preceding claims wherein the light provider and at least one transducer are comprised in a wearable housing.

34. Apparatus according to claim 33 wherein when worn by the patient the housing provides optical and acoustic coupling of the light provider and at least one transducer respectively to the patient's skin.

35. Apparatus according to any of the preceding claims wherein the analyte is glucose.

36. Apparatus for controlling blood glucose level in a patient comprising:
assay apparatus according to claim 35;
an insulin delivery system controllable to administer insulin to a patient;
wherein the controller controls the insulin delivery system responsive to glucose assays provided by the assay apparatus.